

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-853 (MSG)
	)	CONSOLIDATED
AMNEAL PHARMACEUTICALS LLC,	)	
et al.,	)	
	)	
Defendants.	)	

**NOTICE OF SUBPOENA**

PLEASE TAKE NOTICE that the subpoena attached hereto as Exhibit 1 will be served upon Slate Run Pharmaceuticals, LLC.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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July 30, 2020

# EXHIBIT 1

## UNITED STATES DISTRICT COURT

for the

District of Delaware

Amgen Inc.

Plaintiff

v.

Amneal Pharmaceuticals LLC, et al.

Defendant

Civil Action No. 16-853 (GMS)

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To:

Slate Run Pharmaceuticals, LLC  
Corporation Trust Center 1209 Orange St., Wilmington, DE 19801

(Name of person to whom this subpoena is directed)

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

See Exhibit B, attached.

Place: By Video

Date and Time:

August 18, 2020 or at a date and time agreed upon

The deposition will be recorded by this method: Stenography and video

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material: See Exhibit A, attached.

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 07/30/2020

CLERK OF COURT

OR

/s/ Joshua I. Rothman

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) Amgen Inc.,  
\_\_\_\_\_, who issues or requests this subpoena, are:

Joshua I. Rothman, 1290 Avenue of the Americas, New York, NY 10104, JRothman@venable.com, 212.218.2275.

## Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 16-853 (GMS)

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

I received this subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named individual as follows: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_  
\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc.:

**Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)****(c) Place of Compliance.**

**(1) For a Trial, Hearing, or Deposition.** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
  - (i) is a party or a party's officer; or
  - (ii) is commanded to attend a trial and would not incur substantial expense.

**(2) For Other Discovery.** A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

**(d) Protecting a Person Subject to a Subpoena; Enforcement.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

**(e) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(g) Contempt.**

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

# EXHIBIT A

**EXHIBIT A – DOCUMENT REQUESTS FOR SLATE RUN**

**DEFINITIONS**

1. The “Amgen v. Amneal et al. case” means Civil Action No. 16-853-MSG (D. Del.), entitled *Amgen Inc. v. Amneal Pharmaceuticals LLC, et al.*, and identified in the attached subpoena.

2. The following definitions are for purposes of the attached subpoena only directed to Slate Run in connection with the Amgen v. Amneal et al. case.

3. “Amgen” means Amgen Inc.

4. “Slate Run” means Slate Run Pharmaceuticals, LLC (a marketing partner of Piramal), and its officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Slate Run.

5. “Piramal” means collectively, jointly, and severally Piramal Healthcare UK Limited, and each of its respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Piramal Healthcare UK Limited.

6. “Cardinal Health” means collectively, jointly, and severally Cardinal Health, Inc., and each of its respective officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Cardinal Health, Inc.

7. “ANDA” means Abbreviated New Drug Application, as used in 21 U.S.C. § 355(j) and all regulations issued by the FDA pursuant thereto.

8. “Piramal’s ANDA” means ANDA No. 210207 and any amendments thereto.

9. “Piramal’s ANDA Products” means the Cinacalcet hydrochloride oral tablets, 30 mg, 60 mg and 90 mg dosage strengths, which are the subject of Piramal’s ANDA.

10. “Cinacalcet hydrochloride” means ((R)-N-(3-(3-(trifluoromethyl)phenyl)propyl)-1-(1-naphthyl)ethylamine hydrochloride.

11. “Excipient” means any component of Piramal’s ANDA Products that is not the API.

12. “Sensipar®” means the cinacalcet hydrochloride tablets 30 mg, 60 mg, and 90 mg dosage strengths, sold under New Drug Application No. 21-688.

13. “The ’405 patent” means United States Patent No. 9,375,405.

14. “Document” is defined to be synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure, including, without limitation, electronic or computerized data compilations. A draft or non-identical copy is a separate document within the meaning of this term.

15. The term “thing” means any physical specimen or other tangible item other than a document.

16. The term “concerning” means in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

17. The terms “and” and “or” shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.



18. The term “all” means all and each and the term “each” means each and all so that the fullest disclosure of information is achieved.

19. The singular includes the plural and the plural includes the singular so that the fullest disclosure of information is achieved.

20. The “Cipla Case” means *Cipla Ltd. and Cipla USA, Inc. v. Amgen Inc.*, case number 19-044-LPS.

### **INSTRUCTIONS**

1. Pursuant to Rule 45 of the Federal Rules of Civil Procedure, Slate Run is requested to respond within 14 days from the date of service of this subpoena.

2. These discovery requests shall be deemed continuing, requiring Slate Run to produce additional documents and things promptly if Slate Run obtains additional documents and things at any time between the time of the initial production and the time of hearing or trial.

3. If Slate Run has a good faith objection to any request or any part thereof, the specific nature of the objection and whether it applies to the entire request or to a part of the request shall be stated. If there is an objection to any part of a request, then the part objected to shall be identified and documents responsive to the remaining unobjectionable part of the request shall be produced.

4. Each request shall be answered on the basis of Slate Run’s entire knowledge, from all sources, after an appropriate good faith inquiry has been made and a search has been conducted.

5. If Slate Run withholds information on the grounds of attorney-client privilege, work product immunity or any other privilege or immunity, Slate Run must identify the nature of the privilege which is being claimed, and if the privilege is being asserted in connection with a

claim or defense governed by state law, set forth the state privilege rule being invoked; and must provide:

- (a) the type of document, *e.g.*, letter or memorandum;
- (b) the general subject matter of the document;
- (c) the date of the document; and
- (d) such other information as is sufficient to identify the document, including

where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and where not apparent, the relationship of the author, addressees, and recipients to each other.

6. If Slate Run contends that information responsive to any discovery request is incomplete, then Slate Run must provide all responsive information of which Slate Run is now aware.

7. For any document requested herein that has been destroyed, transferred or lost, Slate Run shall identify the document and provide a brief explanation of the circumstances (*e.g.* when, how, by whom, and why) surrounding the document's destruction, transfer or loss, and any and all records pertaining to its destruction, transfer or loss.

8. If Slate Run or Slate Run's attorneys know of the existence, past or present, of any document or thing called for in a request, but such document or thing is not presently in Slate Run's possession, custody, or control or in the possession, custody, or control of its agents, representatives or attorneys, Slate Run shall so state in response to the request, identify such document or thing in response to the request and identify the individual in whose possession, custody, or control the document or thing was last known to reside.

9. Documents and things must be produced as they are maintained in the normal course of business and:

(a) all associated file labels, file headings thereon and file folders shall be produced together with the responsive documents from each file;

(b) all documents that cannot be legibly copied shall be produced in their original form; otherwise, Slate Run may produce photocopies; and

(c) each page shall be given a discrete production number.

### **REQUESTED DOCUMENTS**

1. All documents and things concerning Slate Run's role in the manufacturing, marketing, distribution, and/or sale of Piramal's ANDA Products, and how much Slate Run was paid in connection with such role by Piramal, including, but not limited to, communications and agreements with Piramal or other third parties.

2. All documents and things concerning communications between Slate Run, Piramal, and Slate Run's customers, including, but not limited to, communications concerning Piramal's ANDA Product inventory, when Piramal's ANDA Products were sold, and when Piramal's ANDA Products were not sold.

3. All documents and things sufficient to identify, by each customer of Piramal's ANDA Products:

a. the monthly sales and sale price for each strength of Piramal's ANDA Products sold in the United States from the date of first sale to the present;

b. each product sold by number, SKU, or other applicable identifier;

c. the total number of tablets and bottles sold in the United States; and

d. total gross revenues, net revenues for each product and each time period, including detail of any discounts to bridge gross revenues and net revenues.

4. All documents and things concerning the profits derived from, and the costs of goods attributed to, the sales of Piramal's ANDA Products in the United States from the date first sold to the present, including identification of each product sold by number, SKU, or any other applicable identifier, and the number of units sold monthly, the prices of product sold, gross sales to customers, any deductions from the gross sales invoiced to the customers, the transfer price Slate Run paid Piramal, the cost of goods sold, and the amount Slate Run paid Piramal, including, but not limited to, as part of any profit sharing agreement.

5. All contracts concerning the manufacture, marketing, sale, and/or distribution of Piramal's ANDA Products between Slate Run and Piramal, or any other third party with which Slate Run or Piramal has such a contract, including, but not limited to, any amendments, modifications, or other change documents to such contracts to address other generic entry into commercial competition with Piramal's ANDA Products, including, but not limited to, contracts with Piramal entitled Mutual Confidentiality and Non-Disclosure Agreement effective August 8, 2015 and the License, Manufacturing and Distribution Agreement effective April 3, 2017, wholesale customers, retail customers, group purchasing organizations, and third party formularies.

6. All documents and things concerning the market for Sensipar®, Piramal's ANDA Products, and/or any other generic cinacalcet product, including, but not limited to, competitive intelligence, correspondence, studies, market research reports, market surveys, market projections, revised market projections, and meeting minutes.

7. Documents sufficient to identify all customers for Piramal's ANDA Product.

8. All documents concerning any forecasts, plans, projections, and/or reports that assess the impact of generic entry into commercial competition for cinacalcet hydrochloride products, including but not limited to any such documents concerning:

- a. anticipated and/or actual timing of generic entry;
- b. number of competitors at various dates;
- c. anticipated and/or actual generic penetration/conversion rates;
- d. pricing/market share;
- e. any studies, research papers, analogs (i.e. any potentially comparable drug launches identified), etc. that were used to develop assumptions or variables used in the forecasts, plans, and/or projections.

9. All documents concerning, analyzing, or projecting the effect of any competing generic cinacalcet hydrochloride products offering by any other entity on the number of units sold, gross sales, net sales, gross income, net income, profit, market share, sales prices, and list prices of Piramal's ANDA Product.

10. All documents concerning the actual and/or forecasted size of the market for cinacalcet products, including but not limited to the following topics:

- a. forecasted trends in market units;
- b. expected and/or actual size of the overall market;
- c. expected and/or actual size of the generic market; and
- d. analysis of IQVIA (or other third party data providers) market size.

11. All documents and communications concerning an assessment of the expected or actual impact of the launch of generic cinacalcet products on the demand for cinacalcet

hydrochloride products and on Piramal's ANDA Product market share, including, but not limited to, competitive intelligence, forecasts, market studies, correspondence, surveys, and emails.

12. All documents concerning an estimate, model, and/or report of the anticipated and/or actual impact on Piramal's ANDA Product of the launch of another generic cinacalcet product, including but not limited to a generic cinacalcet hydrochloride product launched at-risk.

13. All documents concerning forecasted or actual market share and sales of Piramal's ANDA Product and other generic cinacalcet hydrochloride products, including, but not limited to, any revised projections for sales of Piramal's ANDA Product.

14. All documents concerning forecasted or actual pricing of Piramal's ANDA Product, including, but not limited to, market studies, correspondence, agreements, surveys and emails.

15. All documents concerning preferences of participants in the pharmaceutical market to switch from branded products to a generic of a branded product, including but not limited to surveys, publications, pharmacy practices, consumer practices, and the likelihood of switching from branded to generic products.

16. All documents concerning any potential strategy considered, or actual strategy implemented, by Slate Run and Piramal to mitigate the impact of the launch of another generic cinacalcet hydrochloride product, including but not limited to:

a. all documents concerning a plan for responding to the launch of another generic cinacalcet hydrochloride tablets in the U.S. including any marketing plans, brand plans, business plans, strategic plans, projections, and/or competitive analysis;

b. all documents concerning a potential at-risk launch of another generic product not authorized by Amgen;

c. all documents concerning a plan to or consideration of reducing the price of Piramal's ANDA Product (through changes to actual pricing or increased discounts) to gain or maintain market share;

d. all documents concerning a plan to or consideration of the use of coupons, financial incentives, promotions, or other direct consumer initiatives to help maintain sales and market share;

e. all documents concerning the benefit of a "first-mover" or "early-mover" advantage (i.e. being the first or one of the first generic entrants and any longer-term benefits of such); and

f. all documents concerning the launch date for Piramal's ANDA Product.

17. All documents concerning the actual or forecasted pricing of Piramal's ANDA Products, including any actual or forecasted changes to pricing, discounts, rebates, or other incentives over time, including but not limited to any changes forecasted or implemented to minimize the impact of the launch of other generic cinacalcet product.

18. All documents concerning Slate Run's knowledge of generic competitor launch timing and/or expectations/forecasts as to when various generic competitors were ready to launch, expected to launch, or did launch.

19. All documents and things concerning the forecast or actual market, sales, profits, and/or market share of an authorized generic cinacalcet hydrochloride product, and unauthorized generic cinacalcet hydrochloride product.

20. All documents and things concerning the inventory of Piramal's ANDA Products, capacity, and manufacturing conditions/constraints before and during the injunction period.

21. All documents concerning Slate Run's efforts to increase customer demand from other generic cinacalcet hydrochloride products to Piramal's ANDA Products.

22. All documents concerning plans or efforts to reduce the price of Piramal's ANDA Products in view of entry by other generics, including but not limited to any related communications or contracts with wholesalers, distributors, pharmacies, retailers and other purchasers of Piramal's ANDA Products.

23. All documents concerning Piramal and Slate Run's capacity or ability to meet market demand for Piramal's ANDA Products.

24. All documents concerning studies, surveys, analyses, and/or evaluations referring or relating to prescriber behavior and/or prescriptions for Sensipar®, Piramal's ANDA Product, or any other generic cinacalcet tablets, including, but not limited, to customer feedback, medical reports, market research surveys, and market analyses.

25. All documents concerning studies of, analyses of, evaluations of, and communications with payors, including without limitation health plans, pharmacy benefit managers, and hospitals, regarding formulary changes with respect to Sensipar®, Piramal's ANDA Product, or other generic cinacalcet tablets.

26. Documents sufficient to identify the market in which Piramal's ANDA Product competes, including, but not limited to, any documents regarding the products and/or companies identified as competitors for Piramal's ANDA Products, information from data aggregators, competitive intelligence, market studies, marketing plans, marketing studies, and surveys which provide information regarding the competitors for Piramal's ANDA Product.



27. Public statements or press releases that address the anticipated impact or actual impact to Amgen, Piramal, Slate Run, or to the cinacalcet hydrochloride market due to the launch of generic cinacalcet tablets.

28. All documents and things related to Slate Run's or Piramal's communications with other generic cinacalcet hydrochloride manufacturers.

29. All documents and things related to the analysis of how a decision in the Cipla Case in favor of Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") would affect Piramal and Slate Run given Cipla's settlement with Amgen, including, but not limited to, Piramal and Slate Run's market share, sale strategy, projected or actual sales, revenues, costs, and Piramal's ANDA Product pricing.

30. All documents and things related to how a decision in the Cipla Case would affect other generic cinacalcet hydrochloride manufacturers, including, but not limited to, their marketing strategies, market share, revenues, costs, and pricing.

31. All documents and things related to how Piramal and Slate Run's economic prospects would change if Cipla prevailed in the Cipla Case versus a situation in which Amgen prevailed in the Cipla Case, including, but not limited to, Piramal and Slate Run's market share, sales, revenues, costs, and Piramal's ANDA Product pricing.

32. All documents and things related to communications with Cardinal Health, including, but not limited to, the amount of sales made to Cardinal Health, the sale price for each strength of Piramal's ANDA Product sold to Cardinal Health, when Piramal's ANDA Product was sold to Cardinal Health, and the amount of product returned from Cardinal Health, and the reasons for the return.

33. All documents and things related to communications with Slate Run or Piramal's potential customers concerning cinacalcet, including but not limited to, CVS Pharmacies, McKesson, DaVita, Fresenius and Kroger, including but not limited to, any discussion related to a desire to purchase Piramal's ANDA Product from Slate Run/Piramal.

34. All documents and things related to the size of Piramal and Slate Run's launch of Piramal's ANDA Product prior to the order granting injunction (D.I. 462), including, but not limited to, the reason for the size of the launch and the capacity for Piramal and Slate Run to sell more.

35. All documents and communications among Slate Run, Piramal, and/or Cardinal Health concerning the timing and amount of sales of Piramal's ANDA Product, including the reasoning for the timing and amount.

36. All documents and things sufficient to show the market size for cinacalcet hydrochloride products, for both Sensipar® and generics, from December 2018 until April 22, 2020.

37. All documents and things related to communications with Slate Run's investors concerning cinacalcet, including, but not limited to, the amount of at-risk sales Slate Run may make of Piramal's ANDA Product, the potential liability for those sales, and strategies implemented or contemplated to avoid the potential liability, including, but not limited to, agreements with investors, and communications with third parties.

38. All documents and things related to the calculation of cost of goods sold (COGS) and transfer price for Piramal's ANDA Product, including, but not limited to, costs of raw materials, manufacturing and production costs, labor costs, transportation costs, variable sales,

distribution costs, and costs of transferring goods between Piramal and Slate Run, or any other third party.

# EXHIBIT B

**EXHIBIT B – DEPOSITION TOPICS:**

**DEFINITIONS**

Amgen Inc. hereby incorporates by reference its definitions in Exhibit A to this subpoena.

**TOPICS**

**TOPIC NO. 1:**

Any sales of cinacalcet hydrochloride lost by Slate Run and/or Piramal as a result of the injunction pending appeal (Civil Action No. 16-853-MSG, D.I. 462), and any profits lost by Slate Run and/or Piramal as a result of those lost sales, and the identification and location of any documents related thereto.

**TOPIC NO. 2:**

The sales of Piramal's ANDA Products in the United States from the date first sold to the present, including the identification of each product sold by number, SKU, or any other applicable identifier, and number of units sold monthly, the price of product sold, gross sales invoiced to customers, any deductions from the gross sales invoiced to customers, the transfer price Slate Run paid Piramal, the cost of goods sold, total gross and net revenues for each product, and the amount Slate Run paid Piramal, including, but not limited to, as part of any profit sharing agreement.

**TOPIC NO. 3:**

The monthly, annual, and total revenues derived from and the costs attributed to the sales described in Topic No. 2.

**TOPIC NO. 4:**

Contracts concerning the manufacture, sale, marketing, and/or distribution of Piramal's ANDA Products between Slate Run and Piramal, or any other third party with which Slate Run or Piramal has such a contract, including but not limited to any amendments, modifications, or other change documents to such contracts to address other generic entry into commercial competition with Piramal's ANDA Products, including, but not limited to, contracts with Piramal entitled Mutual Confidentiality and Non-Disclosure Agreement effective August 8, 2015 and the License, Manufacturing and Distribution Agreement effective April 3, 2017, wholesale customers, retail customers, group purchasing organizations, and third party formularies.

**TOPIC NO. 5:**

Slate Run's role in the manufacturing, marketing, distribution, and/or sale of Piramal's ANDA Products, and how Slate Run was compensated for its activities in those roles.

**TOPIC NO. 6:**

The market in which Piramal's ANDA Product competes and the market share Slate Run and Piramal expected to capture, including, but not limited to, any documents regarding the products and/or companies identified as competitors for Piramal's ANDA Products, information from data aggregators, competitive intelligence, market studies, marketing plans, marketing studies, and surveys which provide information regarding the competitors for Piramal's ANDA Product.

**TOPIC NO. 7:**

Communications between Slate Run, Piramal, and Slate Run's customers, including, but not limited to, communications concerning Piramal's ANDA Product inventory, when Piramal's ANDA Products were sold, and when Piramal's ANDA Products were not sold.

**TOPIC NO. 8:**

The anticipated and/or actual impact(s) on Slate Run and Piramal of the launch of other generic cinacalcet hydrochloride products, including, but not limited to, any generic cinacalcet hydrochloride product authorized and/or launched at-risk by another generic, all actions contemplated or undertaken by Slate Run and Piramal to avoid any negative impacts, and all actions contemplated or undertaken by Slate Run and Piramal to gain, maintain, or increase market share.

**TOPIC NO. 9:**

Any decision concerning the sale of Piramal's ANDA Product before Amgen's claim of infringement against Piramal was fully adjudicated.

**TOPIC NO. 10:**

Strategies considered or implemented by Slate Run or Piramal to minimize the negative financial impact to Slate Run and Piramal of the launch of other generic cinacalcet products, including but not limited to changes to the pricing of Piramal's ANDA Product, marketing strategy, and launch date of Piramal's ANDA Product.

**TOPIC NO. 11:**

The impact(s) on Piramal, Slate Run, and other generic cinacalcet hydrochloride manufacturers of a decision in the Cipla Case in favor of Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla"), including, but not limited to, market share, sale strategy, projected or actual sales, revenues, costs, and pricing of generic cinacalcet hydrochloride products.

**TOPIC NO. 12:**

The impact(s) on Piramal and Slate Run's economic prospects if Cipla prevailed in the Cipla Case as opposed to a situation in which Amgen prevailed in the Cipla Case, including, but

not limited to, Piramal and Slate Run's market share, sales, revenues, costs, and Piramal's ANDA Product pricing.

**TOPIC NO. 13:**

Communications with Cardinal Health, including, but not limited to, the amount of sales made to Cardinal Health, the sale price for each strength of Piramal's ANDA Product sold to Cardinal Health, when Piramal's ANDA Product was sold to Cardinal Health, and the amount of product returned by Cardinal Health, and the reasons for the return.

**TOPIC NO. 14:**

Communications with Slate Run or Piramal's potential customers concerning cinacalcet, including, but not limited to, CVS Pharmacies, McKesson, DaVita, Fresenius and Kroger concerning cinacalcet, including but not limited to, any discussion related to a desire to purchase Piramal's ANDA product from Slate Run or Piramal.

**TOPIC NO. 15:**

Forecasted or actual market share and sales of Piramal's ANDA Product and other generic cinacalcet hydrochloride products, including, but not limited to, any revised projections for sales of Piramal's ANDA Product.

**TOPIC NO. 16:**

Communications among Slate Run, Piramal, and/or Cardinal Health concerning the timing and amount of sales of Piramal's ANDA Product, including the reasoning for the timing and amount.

**TOPIC NO. 17:**

The market size for cinacalcet hydrochloride products, for both Sensipar® and generics, from December 2018 until April 22, 2020.



**TOPIC NO. 17:**

Communications with Slate Run's investors concerning cinacalcet, including, but not limited to, the amount of at-risk sales Slate Run might make of Piramal's ANDA Product, the potential patent infringement liability for those sales, and strategies implemented or contemplated to avoid the potential liability, including, but not limited to, agreements with investors, and communications with third parties.

**TOPIC NO. 18:**

The calculation of cost of goods sold (COGS) and transfer price for Piramal's ANDA Product, including, but not limited to, costs of raw materials, manufacturing and production costs, labor costs, transportation costs, variable sales, distribution costs, and costs of transferring goods between Piramal and Slate Run, or any other third party.

**TOPIC NO. 19:**

The identity and location of any documents related to the subject matter of TOPIC NOS. 1-18.

**TOPIC NO. 20:**

The identity and location of all persons with knowledge of the subject matter of TOPIC NOS. 1-18.

**TOPIC NO. 21:**

The subject matter, content, and authenticity of all documents and things produced by Slate Run in response to Amgen's document requests specified in Exhibit A.

**CERTIFICATE OF SERVICE**

I hereby certify that on July 30, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 30, 2020, upon the following in the manner indicated:

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*/s/ Jack B. Blumenfeld*

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